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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,955	04/12/2004	Dennis Kujawski	760-184	3611

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EXAMINER	
WOLLSCHLAGER, JEFFREY MICHAEL	
ART UNIT	**PAPER NUMBER**
1732	

DATE MAILED: 11/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/822,955	KUJAWSKI, DENNIS	
	Examiner	Art Unit	
	Jeff Wollschlager	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *9-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I Species A, claims 1-8, in the reply filed on October 20, 2006 is acknowledged. The traversal is on the ground(s) that 1) the examiner has not alleged why the inventions are distinct either for the restricted group or species and 2) there is not a serious burden on the examiner to search the multiple inventions. This is not found persuasive because 1) the examiner provided in the original restriction that the method can be practiced by another and materially different apparatus, such as an apparatus not employing a source of ultrasonic energy. Further, the species requirement is at least regarding the mandrel where in Species A, the mandrel has a curved crimping surface and in Species B, the mandrel is cylindrical and employs a slidable mandrel donut. These are mutually exclusive embodiments. 2) Further, the traversal is on the ground(s) that searching the distinct inventions would not create an undue burden on the examiner due to an overlapping search. This is not found persuasive because the specifics to examine a process, namely the stepwise claim limitations and the material undergoing a change in physical or chemical state are not required when examining an apparatus or product, which are limited only by structural limitations. Although a process claim may contain apparatus or article limitations, they are only given patentable weight as to how the structure affects the stepwise process. Similarly, the specifics of an apparatus or article do not require the same consideration of stepwise process limitations as in a process claim, but rather only that the structure is capable of performing or being produced by such a process

step. Additionally, regarding the species restriction of the method claims, there is a serious burden on the examiner because the mutually exclusive limitations require a different search.

The requirement is still deemed proper and is therefore made FINAL.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the application admits of illustration by clear drawings to facilitate understanding of the invention. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: Reference is made to co-pending applications (paragraph [0025] in US Patent Application Publication 2005/0228489). These co-pending applications should be referred to by application and/or patent number. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the manipulative step between "positioning" and the resulting "contours to said curved crimping surface". For the purposes of examination, the claim is interpreted in view of the dependent claims which appear to provide the omitted step(s). Claims 6-8 are unclear because the term "horn" is unclear as to its limiting effect. For the purposes of examination the term is understood to be "ultrasonic horn". Further, claims 6-8 are unclear as to whether the horn is providing the "ultrasonic action to heat set crimps thereat". Claim 8 is indefinite because the recitation, "said rotatable mandrel made to rotate" lacks antecedent basis. It is also unclear in claim 8, whether the horn and the mandrel actually rotate. For the purposes of examination, the recitation, "made to rotate" is understood to mean the horn and/or mandrel rotate to crimp around the graft.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raible (U.S. Patent 4,512,761) in view of Casey, et al. (US 2004/0019375) and/or Gabbay (US 2002/0036220) and/or Schmitt et al. (US Patent 6,187,033) and/or Nunez et al. (US 2003/0078650).

Regarding claims 1-3, Raible teaches a tubular graft of unitary fiber construction having an enlarged bulbous portion disposed between tubular ends, wherein the diameter of the bulbous section is greater than the diameter of the tubular ends (col. 2, lines 29-57). Raible does not expressly state the fibrous graft is flat-woven nor does he teach crimping the surface as claimed. However, the cited secondary references teach flat-woven tubular grafts that have varying diameters, sizes and shapes, including illustrated sections with a center section having a larger diameter than the tubular ends, that are crimped with a mandrel having a curved crimping surface that is positioned within the graft at desired locations so that the woven sections contour to said curved crimping surface. The contours/crimps are set by applying heat and/or pressure.

(Casey: Figures 1-3, paragraphs [0025-0027]; Gabbay: Figure 10, paragraph [0047]; Schmitt: Figure 2, col. 4, line 65 – col. 5, line 4, col. 7, lines 48-61, col. 9, lines 1-8; Nunez: paragraphs [0015, 0018, 0061, 0056-0068]).

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to employ a conventional flat-woven tubular graft and to crimp the surface as claimed in the graft disclosed by Raible and the secondary references for the purpose of providing a graft with increased strength that is less likely to kink or collapse and with added flexibility as taught by the cited references.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raible (U.S. Patent 4,512,761) in view of Casey, et al. (US 2004/0019375) and/or Gabbay (US 2002/0036220) and/or Schmitt et al. (US Patent 6,187,033) and/or Nunez et al. (US 2003/0078650), as applied to claims 1-3 above, in view of Stokes et al. (US Patent 5,814,390) or Rosenstein et al. (U.S. Patent 3,230,598) or LeVeen (U.S. Patent 3,317,924).

As to claim 4, Raible in view of the secondary references teach the method of claim 1 as discussed above. Further, Nunez discloses that a variety of heating setting means known in the art may be employed to heat set the crimps [paragraphs [0061-0062], but does not expressly disclose ultrasonic action for heat setting the crimps in the graft. However, Stokes (col. 5, line 55-col. 6, line 36), Rosenstein (col. 1, lines 20-35; col. 4, lines 38-50), and LeVeen (col. 1, lines 8-69) each provide individual and

analogous heat setting methods wherein the heat setting is performed through ultrasonic means.

Therefore it would have been *prima facie* to one having ordinary skill in the art at the time of the claimed invention to employ conventional and art recognized equivalent means for heating setting, as suggested by Nunez and taught individually by Stokes, Rosenstein and LeVeen for the purpose of productivity enhancement, cost control, and convenience.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raible (U.S. Patent 4,512,761) in view of Casey, et al. (US 2004/0019375) and/or Gabbay (US 2002/0036220) and/or Schmitt et al. (US Patent 6,187,033) and/or Nunez et al. (US 2003/0078650), as applied to claims 1-3 above, in view of Gantt et al. (US 2003/0109919).

As to claim 5, Raible in view of the secondary references teach the method of claim 1 as discussed above. Further, Nunez discloses that a variety of heating setting means known in the art may be employed to heat set the crimps [paragraphs [0061-0062], but does not expressly disclose steam for heat setting the graft. However, Gantt et al. teach an analogous heat setting method wherein the heat setting is performed with steam (paragraph [0053]).

Therefore it would have been *prima facie* to one having ordinary skill in the art at the time of the claimed invention to employ conventional and art recognized equivalent

means for heating setting, as suggested by Nunez and taught by Gantt et al. for the purpose of productivity enhancement, cost control, and convenience.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raible (U.S. Patent 4,512,761) in view of Casey, et al. (US 2004/0019375) and/or Gabbay (US 2002/0036220) and/or Schmitt et al. (US Patent 6,187,033) and/or Nunez et al. (US 2003/0078650), as applied to claim 1-3 above, further in view of Stokes et al. (US Patent 5,814,390) or Rosenstein et al. (U.S. Patent 3,230,598) or LeVeen (U.S. Patent 3,317,924) and still further in view of Ultrasonic Processing of Fabric and Film (Dukane Corporation, Technical Bulletin from website in December 2003).

As to claim 6, Raible in view of the secondary references teach the method of claim 1 as discussed in the rejection above and Stokes, Rosenstein or LeVeen further teach heat setting with ultrasonic means as discussed in the rejection of claim 4 above, but the combined references do not teach how the ultrasonic means are expressly employed. However, Ultrasonic Processing of Fabric and Film provides details of a plunge method for embossing/crimping fabrics and films in medical applications (page 1, first paragraph; page 2, "Plunge Mode" section and Figure; page 4, Fabrics-Woven)

Therefore it would have been *prima facie* obvious to one having ordinary skill in the art at the time of the claimed invention to employ the specific ultrasonic means disclosed by Ultrasonic Processing of Fabric and Films to crimp/emboss the graft disclosed by Raible for the purpose of creating a graft with increased strength that is less likely to kink or collapse and with added flexibility as taught by the cited references

Allowable Subject Matter

Claims 7 and 8 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Conclusion

All claims are rejected.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Wollschlager whose telephone number is 571-272-8937. The examiner can normally be reached on Monday - Thursday 7:00 - 4:45, alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JW

Jeff Wollschlager
Examiner
Art Unit 1732

November 2, 2006

CHRISTINA JOHNSON
SUPERVISORY PATENT EXAMINER

11/13/06